REMARKS/ARGUMENTS

Claims 21-35 are pending, claims 25-35 having been withdrawn from consideration. By this Amendment, claim 25 is amended. Support for the amendments to claim 25 can be found, for example, in the present specification at page 23, lines 16 to 21, and in previously presented claim 25. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

Personal Interview

Applicants appreciate the courtesies extended to Applicants' representative by Examiners Palenik and Wax during the July 29, 2011 Personal Interview. Applicants' separate record of the substance of the interview is incorporated in the following remarks.

Withdrawn Claims

For the reasons set forth below, Applicants submit that all pending claims presently subject to examination are in condition for allowance. Because the withdrawn claims depend from, and thus recite all features of, allowable claim 21, rejoinder and allowance of the withdrawn claims are respectfully requested.

Rejection Under 35 U.S.C. §103

The Office Action rejects claims 21-24 under 35 U.S.C. §103(a) over U.S. Patent Application Publication No. US 2004/0058956 to Akiyama et al. ("Akiyama") in view of U.S. Patent No. 6,753,330 to Takano et al. ("Takano") and Sylysia FCP Brochure ("Fuji"). Applicants respectfully traverse the rejection.

Claim 21 recites "[a] composition, comprising: an extremely poorly water-soluble drug; and a porous silica material; wherein: the composition is obtained by treating a mixture

comprising the porous silica material and the extremely poorly water-soluble drug with a supercritical fluid or subcritical fluid of carbon dioxide; the extremely poorly water-soluble drug has a solubility in water at 25 °C of less than 10 μg/mL prior to treatment; the porous silica material has an average pore diameter of from 1 to 20 nm, a total pore volume of pores having diameters within ±40% of the average pore diameter accounts for at least 60% of a volume of all pores of the porous silica material, and the porous silica material has an X-ray diffraction pattern including at least one peak at a position of a diffraction angle (2θ) corresponding to a *d* value of at least 1 nm; and the composition is suitable for oral administration" (emphasis added). Akiyama, Takano, and Fuji do not disclose or suggest such a composition.

It is undisputed that none of the cited references discloses or suggests a composition including a mixture of an extremely poorly water-soluble drug and a porous silica material, which is obtained by treating the mixture with a supercritical or subcritical carbon dioxide fluid. The Office Action asserts that this feature (treating the mixture with a supercritical or subcritical carbon dioxide fluid) should be given no weight as it is a product-by-process feature. *See* Office Action, pages 7 to 8. While "the patentability of a product does not depend on its method of production," it is also true that the structure implied by process steps should be considered when assessing patentability. *See* MPEP §2113. In this case, by treating the mixture with a supercritical or subcritical carbon dioxide fluid, a composition is obtained that has different properties from composition that is not obtained by being subjected to such a treatment.

As agreed during the Personal Interview, the experimental results in the present specification confirm the foregoing assertion. *See* present specification, TABLE 1 (reproduced below). For example, Example 1 and Comparative Example 1 include the same extremely poorly water-soluble drug and the same porous silica materials in the same

amounts. The two compositions differ in that, the composition of Example 1 was obtained by mixing in the presence of dry ice (as required in claim 21), while the composition of Comparative Example 1 was prepared without dry ice (as in, e.g., Akiyama). By virtue of the manner in which the respective compositions were obtained, the composition of Example 1 is substantially more soluble (at each of 5, 30, 60, and 120 minute stirring times). Thus, compositions according to claim 21 are substantially more soluble than otherwise identical compositions that are not obtained by treating a mixture of an extremely poorly water-soluble drug and a porous silica material with a supercritical or subcritical carbon dioxide fluid.

TABLE 1

		Example		Comparative Example	
		1	2	1	2
Compound A (mg)		30	30	30	30
"FSM-C16" (mg)		300	—	300	—
"FSM-C12" (mg)		—	300	—	—
Dry ice (g)		120	120	—	120
Average pore diameter (nm)		3	2	3	—
Dissolution rate (%)	Stirring time (min)				
	5	29.5	22.0	3.9	0.0
	30	54.8	40.7	7.6	1.7
	60	63.9	51.2	10.0	1.1
	120	74.7	57.2	14.3	2.2

Accordingly, even if the cited references were deemed to suggest a mixture of an extremely poorly water-soluble drug and a porous silica material as required in claim 21, because the cited references indisputably fail to disclose or suggest treating the mixture with a supercritical or subcritical carbon dioxide fluid, the cited references fail to disclose or suggest a composition having the properties of the composition of claim 21.

As explained, claim 21 would not have been rendered obvious by Akiyama, Takano and Fuji. Claims 22-24 depend from claim 21 and, thus, also would not have been rendered obvious by Akiyama, Takano and Fuji. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

For the foregoing reasons, Applicants submit that claims 21-35 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

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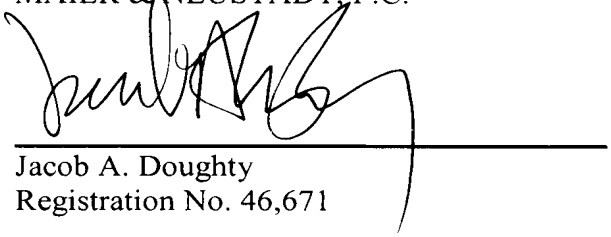

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